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SUPPLEMENT ARTICLE

Inequalities in Health Impact of Alternative Reimbursement Pathways for Nirsevimab in the United States

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The target populations and financing mechanisms for a new health technology may affect health inequalities in access and impact. We projected the distributional consequences of introducing nirsevimab for prevention of respiratory syncytial virus in a US birth cohort of infants through alternative reimbursement pathway scenarios. Using the RSV immunization impact model, we estimated that a vaccine-like reimbursement pathway would cover 32% more infants than a pharmaceutical pathway. The vaccine pathway would avert 30% more hospitalizations and 39% more emergency room visits overall, and 44% and 44%, respectively, in publicly insured infants. The vaccine pathway would benefit infants from poorer households.

Keywords. infants; insurance; United States; respiratory syncytial virus infections; lower respiratory tract infections; health care utilization; equity; model.

Respiratory syncytial virus (RSV) is a seasonal virus typically circulating during cooler months in temperate countries, with notable geographic variation [1]. In the United States, it is a common cause of bronchiolitis and pneumonia in children younger than 1 year of age, leading to a high burden in hospitalizations [2–4]. Two-thirds of those hospitalized infants do not have underlying conditions or risk factors [3, 4]. However, palivizumab, the current standard of care for the prevention of serious lower respiratory tract infections (LRTIs) caused by RSV, is recommended only in preterm infants born at 29 weeks or less of gestational age, and those with comorbidities such as chronic lung disease of prematurity and congenital heart disease. Palivizumab, a monoclonal antibody with a 28-day duration of protection administered in 5 intramuscular doses across the RSV season, has been approved since 1999 [5, 6]. Currently, this immune prophylaxis is accessed through a reimbursement pathway used for pharmaceuticals. Access and households' costs vary with individual insurance coverage [7–10]. Insurers may restrict access to administration with the RSV season, establish strict eligibility criteria, and require authorization prior to use. Some commercial insurers could further deny coverage based on the infant's benefit plan.

There have been recent advances in the development of both vaccines and immune prophylaxis products for RSV prevention. Nirsevimab, a long-acting monoclonal antibody with an extended half-life, is being developed to protect infants from RSV with a single intramuscular dose. It has been shown to reduce medically attended RSV-associated LRTIs and hospitalizations compared with placebo in preterm, healthy late preterm, and term infants during their first RSV season [11–13]. If this product were licensed, the Advisory Committee on Immunization Practices (ACIP) might then provide use recommendations [14]. A broad recommendation for use among infants in all groups independent of risk, whether they are born in or out of season, could be considered by ACIP given nirsevimab's safety, efficacy, and administration profile. A reimbursement pathway akin to a traditional vaccine pathway, such as coverage through the Vaccine For Children program [15], could minimize inequalities in access and health outcomes. In this study, we aimed to assess the distribution of health benefits across insurance groups when accessing nirsevimab through alternative reimbursement pathways.

METHODS

We applied a publicly available spreadsheet-based tool, the RSV immunization impact model (RSV I^2M), to estimate the impact of immunization strategies on RSV-associated medically attended LRTIs among infants across US health care settings: inpatient hospitalization, emergency department visits, and outpatient visits [16]. For this analysis, we modelled the

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introduction of nirsevimab in a US birth cohort of infants younger than 12 months. We further classified infants according to their insurance coverage. Table 1 presents access conditions to pharmaceuticals and vaccines by type of insurance. Uninsured or underinsured infants are included in the table for completeness but excluded from the analysis. In the RSV I^2M tool, users can input other model parameters. In Table 2, we list the original inputs for reference [16] and our assumptions by insurance type. We considered 2 groups of infants: a public insurance group, which includes Medicaid and the Children's Health Insurance Program (CHIP), and a commercial insurance group. We did not include uninsured infants, due to the lack of data to specify health care outcomes in this group. Public insurance provides access to health care services to low-income groups (eligibility is state specific). CHIP covers otherwise uninsured children in families with incomes too high to qualify for Medicaid but too low to afford commercial insurance. An infant's benefits vary based on the eligibility pathway through which coverage was obtained. Under traditional Medicaid benefits, prescription drug coverage is an optional benefit, but all states have chosen to offer it. Under alternative benefits plans, prescription drug coverage is a mandatory benefit. Although benefits also vary by state, CHIP and Medicaid prescription drug coverage is generally the same. The commercial insurance group includes private plans that have more flexibility to make coverage and reimbursement determinations. Most private insurance is offered through employers, although Americans can also purchase coverage directly. Under the pharmaceutical pathway, each health insurance plan decides on each drug's coverage and payment criteria. Vaccines are widely available for infants under all these coverage groups.

Table 1. Description of Insurance Coverage by Type of Technology

Insurance Coverage	Pharmaceuticals	Vaccines
Commercial insurance	Prior approval request needed Commercial insurance coverage varies depending on benefits plans and use: if drug is used at birth, it is more likely to be used in inpatient settings and to be covered by birth bundle packages; if drug is used after birth, it is more likely to be billed separately from well-child clinics OOP payments for commercially insured patients reflect benefits variation across plans	No prior approval request needed Covered in commercial insurance, with universal inclusion in benefits No OOP payments for commercially insured patients
Public insurance	Prior approval request needed Medicaid coverage more likely applies if the drug is used in outpatient settings but it may not be a requirement to cover it in inpatient settings No OOP payments for Medicaid Small OOP payments for CHIP	No prior approval request needed Covered through Medicaid/CHIP No OOP payments for Medicaid/CHIP beneficiaries
No insurance	Uninsured not covered	No prior approval request needed Uninsured (and underinsured) infants covered through VFC

The VFC program provides vaccines at no cost to children who are Medicaid-eligible, uninsured, American Indian or Alaska Native, or underinsured and vaccinated at Federally Qualified Health Centers or Rural Health Clinics. Not all children covered through CHIP are eligible for VFC, only infants who are part of Medicaid expansion.

Abbreviations: CHIP, Children's Health Insurance Program; OOP, out of pocket payments; VFC, Vaccines for Children.

We assumed a broad recommendation for use of nirsevimab among all infants, compared with the current recommendation for palivizumab, which covers only premature babies and/or those with comorbidities [6]. Access to nirsevimab is modelled through 2 reimbursement pathway scenarios: (1) a pharmaceutical pathway similar to the current reimbursement pathway for other nonvaccine pharmaceutical products like palivizumab; and (2) a vaccine pathway reflecting current programs to enhance access to vaccines. These scenarios are characterized by the uptake assumptions presented in Table 1. Uptake is defined as the proportion of the eligible population targeted to receive an immunization product and completing the full regimen as prescribed. For palivizumab uptake, we considered the proportion of palivizumab-eligible infants completing the full regimen by type of insurance. For nirsevimab uptake, we examined palivizumab-eligible and other infants separately. Nirsevimab's uptake assumptions for palivizumab-eligible infants were based on the proportion of palivizumab-eligible infants accessing at least 1 dose of palivizumab by insurance type as an analog [8]. Uptake among this group of infants was assumed to be the same in a pharmaceutical or vaccine pathway, assuming the same practice as currently observed. While these assumptions reflect less constraints in access to nirsevimab compared to palivizumab (like the removal of need to adherence to 5 doses), they remain conservative as the lack of preauthorization could be expected to improve uptake further. In the second group, other infants, our uptake assumptions were based on access to similar technologies by most likely place of administration. We explored different places of administration as an immunization product with a broader indication will be available to infants in other settings than in hospitals. Influenza vaccine coverage rates reflect access to vaccines in walk-in clinics, rotavirus vaccine coverage rates reflect access in well-child clinics, and hepatitis B vaccine is usually administered at birth, likely representing access to vaccines at birth inpatient settings [24, 25].

In this analysis, we calculated the use of nirsevimab defined as the number of infants receiving the immunization based on the uptake and size of birth cohort for each access scenario reflecting alternative (pharmaceutical and vaccine) pathways. We

Table 2. Population, RSV, Product-Related and Uptake Inputs by Type of Insurance

Model Input	Rainisch 2020 [16]	Commercial Insurance	Public Insurance	Reference
No. of annual live births[a] (%)	3 458 979 (92.1)	1 881 265 (50.2)	1 577 714 (42.1)	[17]
Births at high-risk for RSV complications, %	0.98	0.84	1.05	[8]
High-risk hospitalized due to RSV before 12 mo, %	9.31	9.2	9.7	[8, 18, 19]
Rates of medically attended RSV infections per 1000 births				
Hospitalizations, mean (95% CI)	8.4 (1.5–30.8)	7.6 (1.4–28.0)	9.2 (1.7–33.9)	[16, 20]
Emergency department visits, mean (95% CI)	66.2 (16.8–132.7)	28.4 (7.2–56.9)	154.5 (39.2–309.6)	
Outpatient clinic visits, mean (95% CI)	230.9 (71.0–337.2)	320.7 (98.6–468.3)	166.2 (51.1–242.8)	
Proportion of RSV visits with a LRTI diagnosis, by 0–5/6–11 mo of age categories				
Hospitalizations	1.00/1.00			[16]
Emergency department visits	0.65/0.50			
Outpatient clinic visits	0.65/0.30			
Case fatality rates of hospitalized cases by infant age, %				
0–5 mo	0.10			[21]
5–11 mo	0.10			
RSV season duration	October-March			[1]
Efficacy associated with full immunization, %				
Palivizumab	51			[22]
Nirsevimab	75,[b] varied in sensitivity analysis			[12, 13, 23]
Duration of protection, d				
Palivizumab	150			[18]
Nirsevimab	150			[13]
Uptake, %				
Palivizumab, high-risk infants, pharmaceutical pathway	38	37	43	[8]
Palivizumab, high-risk infants, vaccine pathway				
Nirsevimab, low-risk infants, pharmaceutical pathway	71	70[c]	50[d]	[24, 25] (varied in sensitivity analysis)
Nirsevimab, low-risk infants, vaccine pathway	85[e]	75[f]		
Nirsevimab, high-risk infants, pharmaceutical pathway	80	80[g]	75[h]	[8]
Nirsevimab, high-risk infants, vaccine pathway				

Those infants considered at high-risk are infants with conditions that put them at high risk of RSV complications like hemodynamically significant CHD, CLD of prematurity, and prematurity (<29 weeks gestation) without CHD or CLD. Low-risk infants are all other infants. There are 2 reimbursement pathways—a pharmaceutical pathway similar to the way palivizumab is currently accessed and a vaccine pathway, which overcomes most barriers to access through programs like Vaccines for Children. The conceptualization of these pathways is described in Table 1.

Abbreviations: CHD, congenital heart disease; CI, confidence interval; CLD, chronic lung disease; LRTI, lower respiratory tract infection; RSV, respiratory syncytial virus.

[a]Total number of annual live births in 2019. The proportions in those subgroups do not add to 100% of total births per year as there is an additional group of infants excluded from the analysis. The group excluded from the analysis covers those infants classified as self-pay (uninsured deliveries) and those covered by other types of insurance, eg, Indian Health Service, CHAMPUS or TRICARE, other government (federal, state, or local), or charity [17].

[b]Vaccine efficacy (reduction in incidence of medically attended RSV-associated LRTI) was reported for nirsevimab at 70.1% (95% CI, 52.3%–81.2%) in healthy preterm infants [13] and 74.5% (95% CI, 49.6%–87.1%) among late preterm and term infants [23].

[c]Influenza vaccine uptake among commercially insured infants: 69.6% (67.7%–71.4%) [25].

[d]Influenza vaccine uptake among publicly insured infants: 49.3% (47.1%–51.6%) [25].

[e]Among commercially insured infants—hepatitis B vaccine uptake: 77.3% (75.6%–78.9%), Rotavirus vaccine uptake: 84.6% (83.2%–85.9%) [24].

[f]Among publicly insured infants—hepatitis B vaccine uptake: 76.3% (74.2%–78.3%), Rotavirus vaccine uptake: 67.5% (65.3%–69.6%) [24].

[g]At least 1 dose of palivizumab among those infants commercially insured: 76.0%–83.1% [8].

[h]At least 1 dose of palivizumab among those infants publicly insured: 74.1%–77.4% [8].

estimated the benefits as the number of outpatient visits averted, emergency department visits averted, and hospitalizations averted in 2 populations: those infants commercially insured and those publicly insured, by alternative reimbursement pathway. The baseline for this comparison reflects the standard of care in which only palivizumab is available to palivizumab-eligible infants. We validated the pathways assumptions by comparing the total benefit and use of nirsevimab with existing assumptions [16]. We then estimated the distribution of nirsevimab incremental use and incremental health benefits by comparing use and benefits in a vaccine reimbursement pathway with those of a baseline of a pharmaceutical reimbursement pathway (ie, reflecting the incremental use and benefits due to the switch from a pharmaceutical to a vaccine reimbursement pathway). Several sensitivity analyses were carried out. Uncertainty in parameters related to burden of disease are reflected in the confidence intervals presented. We also looked at the impact of uncertainty in other parameters such as uptake, RSV burden distribution across health care settings, and nirsevimab's efficacy (see Supplementary Material for inputs of sensitivity analysis, Supplementary Table 5).

RESULTS

Table 3 presents the distribution of use and health benefits by insurance coverage if nirsevimab were introduced in a cohort of infants in the United States under 2 alternative reimbursement pathways. The proportion of commercially insured infants receiving nirsevimab is higher whether nirsevimab is reimbursed through a pharmaceutical or a vaccine pathway compared with the proportion of publicly insured infants accessing nirsevimab. However, the difference between the publicly and the commercially insured groups' use becomes smaller if nirsevimab were reimbursed through a vaccine pathway compared with the pharmaceutical pathway. Commercially insured infants benefit from more outpatient visits being averted,

Table 3. Use of Nirsevimab and Health Benefit Distribution by Reimbursement Pathway and Insurance Coverage

Item	Both Insurance Groups, No. (95% CI)	Commercially Insured Infants, No. (95% CI); Distribution by Insurance Group, %	Publicly Insured Infants, No. (95% CI); Distribution by Insurance Group, %
Pharmaceutical reimbursement pathway			
Use, infants receiving nirsevimab	2 111 464	1 318 466; 62	792 998; 38
Benefit, outpatient visits averted	151 380 (126 140–176 930)	114 860 (95 710–134 250); 76	36 520 (30 430–42 680); 24
Benefit, emergency department visits averted	58 900 (50 420–67 380)	13 580 (11 620–15 530); 23	45 320 (38 800–51 850); 77
Benefit, hospitalizations averted	12 090 (9100–15 530)	6940 (5200–8940); 57	5150 (3900–6590); 43
Vaccine reimbursement pathway			
Use, infants receiving nirsevimab	2 781 571	1 598 285; 57	1 183 286; 43
Benefit, outpatient visits averted	189 700 (158 060–221 720)	137 010 (114 160–160 140); 72	52 690 (43 900–61 580); 28
Benefit, emergency department visits averted	81 580 (69 860–93 350)	16 190 (13 870–18 530); 20	65 390 (55 990–74 820); 80
Benefit, hospitalizations averted	15 710 (11 690–20 320)	8280 (6160–10 710); 53	7430 (5530–9610); 47
Incremental impact, pharmaceutical vs vaccine pathway			
Use, infants receiving nirsevimab	670 106	279 819; 42	390 287; 58
Increase over pharmaceutical pathway, %	32	21	49
Benefit, outpatient visits averted	38 320 (31 920–44 790)	22 150 (18 450–25 890); 58	16 170 (13 470–18 900); 42
Increase over pharmaceutical pathway, %	25 (21–30)	19 (16–23)	44 (37–52)
Benefit, emergency department visits averted	22 680 (19 440–25 970)	2610 (2250–3000); 12	20 070 (17 190–22 970); 88
Increase over pharmaceutical pathway, %	39 (33–44)	19 (17–22)	44 (38–51)
Benefit, hospitalizations averted	3620 (2590–4790)	1340 (960–1770); 37	2280 (1630–3020); 63
Increase over pharmaceutical pathway, %	30 (21–40)	19 (14–26)	44 (32–59)

There are 2 reimbursement pathways—a pharmaceutical pathway similar to the way palivizumab is currently accessed and a vaccine pathway, which overcomes most barriers to access through programs like Vaccines for Children. The conceptualization of these pathways is described in Table 1.

Abbreviation: CI, confidence interval.

whereas publicly insured infants are estimated to benefit more from emergency department visits averted. Both groups benefit similarly from hospitalizations averted. These distributions are similar whether we model a pharmaceutical or a vaccine reimbursement pathway.

When comparing the incremental use and incremental benefits due to an expansion in access (represented by the shift from a pharmaceutical to a vaccine reimbursement pathway), we observed an increase in access for all infants, with a higher increase for use (49% vs 21%) and benefit (44% vs 19%) among publicly insured infants as compared with commercially insured infants, respectively. The shares of the incremental use and the incremental benefits attributable to the shift from a pharmaceutical to a vaccine pathway are illustrated in the percentages in Table 3 (and in Supplementary Figure 1). Although there are fewer publicly insured live births, the shares in incremental use and incremental benefits (emergency visits and hospitalizations averted) are larger among publicly insured infants compared with those commercially insured infants. We also observed commercially insured infants receiving a larger share of those benefits as measured in outpatient visits averted.

We validated these disaggregated results by comparing the use and benefits with the estimates using the original inputs. The resulting aggregated results corresponded to an average of the results by subpopulation (Supplementary Table 4). The sensitivity analysis showed that although our results are robust to the assumptions, the main source of uncertainty is the assumptions of underlying burden distribution of RSV LRTI by health system level (Supplementary Table 6).

DISCUSSION

In our study, the shift from a pharmaceutical to a vaccine reimbursement pathway increases the use and benefit of nirsevimab in both commercially and publicly insured infants, assuming nirsevimab was recommended to all infants. While we observed an increase in access, we also highlighted that this increase was not homogeneous. There was at least twice as much increase in access and benefits among publicly insured infants as compared with that of commercially insured infants. Thus, financing through a vaccine-like reimbursement pathway would be pro equity.

Benefits such as emergency visits and hospitalization averted can translate into substantial cost savings, as these have been shown to be more costly to the health system as well as the patient during and after the acute episode in the United States [26–28]. A recent cost-effectiveness analysis of infants born in October (the start of the RSV season) suggests that nirsevimab would be cost-effective if priced in the range of other innovative pediatric vaccines [29]. The higher uptake for hepatitis B (76%) over rotavirus vaccination (67.5%) among publicly insured infants suggests that immunizing infants born during the RSV season during the birth hospitalization might expand the advantages of the vaccination pathway. Literature describing RSV-specific disparities is limited, but studies describing associated hospitalizations and severity have described that publicly insured children are overrepresented among cases [3, 4, 30]. A recent review of inequality in acute respiratory infection outcomes in the United States showed the burden of respiratory viruses (eg, influenza, RSV, and coronavirus disease 2019 [COVID-19]) to reflect and magnify existing socioeconomic inequalities and at the same time, socioeconomic inequalities as drivers of exposure, severe disease, and mortality [30]. The choice of populations for which a new health technology is recommended and how its delivery is financed may introduce, exacerbate, or attenuate health inequalities in service delivery and access.

However, modeling studies have limitations, and our study is no exception. First, we are modeling reimbursement pathways that are not defined in the current system. Our aim was to illustrate the distributional impact of public subsidy on health care utilization. We focused on the differential impact of additional government spending to achieve objectives such as increasing coverage, reducing inequality in health care use, and increasing financial protection among disadvantaged populations. Further analyses could also quantify the corresponding expansion of government spending needed to achieve the gains in equity we highlighted in this analysis. Second, our impact is driven by uptake assumptions. We aimed to base our assumptions on technological analogs. Once implemented, uptake will become measurable, and this type of analysis could then be grounded on implementation data. Third, we used secondary data and made assumptions to disaggregate to sufficient granularity. One aspect that could be explored further, once evidence of use across age groups becomes available, will be shorter windows of eligibility (ie, 6 months of age or even 3 months). Fourth, we did not consider the possible side effects of the immunization or exposures from additional contacts. Finally, we looked at 2 possible reimbursement pathways that represent the 2 extremes in terms of accessibility. However, there are intermediate solutions, such as access through preventative care legislation paired with the latest health care reforms, that may be an improvement to the current pharmaceutical pathway.

Differences in the distribution of health burden, heterogeneity in access to care, and disparities in the distribution of potential health gains between population groups once a new technology is introduced are aspects of equity of interest to policy makers, and evidence of this type could be helpful when monitoring inequalities in government spending on health.

Supplementary Data

Supplementary materials are available at *The Journal of Infectious Diseases* online (http://jid.oxfordjournals.org/).

Supplementary materials consist of data provided by the author that are published to benefit the reader. The posted materials are not copyedited. The contents of all supplementary data are the sole responsibility of the authors. Questions or messages regarding errors should be addressed to the author.

Notes

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